Regulatory Writer

Job ID
REQ-10048706

4月 16, 2025

India

摘要

To write, review and/or manage the production of high quality clinical and safety documentation for submission to regulatory authorities in support of marketing applications. To provide documentation related consultancy to other line functions.

About the Role

Major accountabilities:

- To author and review high quality clinical and safety documents: non-registration Clinical Study Reports (CSR), Development Safety Update Reports (DSUR), Risk Management Plans (RMP).
  2. Lead for outsourced Narrative projects. Coordinate other outsourced activities in RWS.
  3. Core member of Clinical Trial Team (CTT) / participate in Safety Management Team (SMT).

4. Actively participate in planning of data analyses and presentation used in CSRs.
5. Act as documentation consultant in CTTs and SMTs to ensure compliance of documentation to internal company standards and external regulatory guidelines.
6. May act as Program Writer ensuring adequate medical writing resources are available for assigned program and consistency between documents.
7. Act as liaison between CTTs and publishing teams to ensure timely delivery of final documents for publishing.
8. Support the development of RWS through participating in RWS workstreams and other related activities.
9. Contribute to development of processes within RWS. May contribute to cross-functional initiatives.
10. Fostering cross-functional communication to optimize feedback and input towards high quality documents.
11. Maintain audit, SOP and training compliance.

Key performance indicators:

- Delivery of high quality clinical and safety documents in time and in compliance with internal and external standards -Customer / partner/ project feedback and satisfaction -Adherence to Novartis policy and guidelines

Minimum Requirements:
Work Experience:

- Minimum 3-5 years of medical writing experience or 1-3 years of experience with MBBS/PhD.
- Good knowledge of and some experience in global regulatory environment and process (key regulatory bodies, key documents, approval processes, safety reporting requirements).
- Knowledge of process for and some experience in global registering of drugs (simple submissions).
- Excellent communication skills (written, verbal, presentations) · Very good understanding of biostatistics principles.
- Ability to prioritize and manage multiple demands and projects.
- Ability to define and solve complex problems (“Problemsolver”)
- Broad knowledge and future oriented perspective
- Proven track record in matrix environment
- Experience in contributing to global, cross-functional projects.
- Global, cross-cultural perspective and customer orientation

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部门
Development

Business Unit
Innovative Medicines

地点
India

站点
Mumbai (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Alternative Location 1
Hyderabad (Office), India

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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